SCREENING REPORT

TO ASSESS WHETHER THE USE OF FOUR BENZOTRIAZOLES IN ARTICLES SHOULD BE RESTRICTED IN ACCORDANCE WITH REACH ARTICLE 69(2)

Annex XIV entry	Substance name	Abbreviation	EC	CAS	Latest application date	Sunset date	Intrinsic property
51	2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol	UV-328	247-384-8	25973-55-1	27-May-2022	27-Nov-2023	PBT vPvB
52	2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol	UV-327	223-383-8	3864-99-1	27-May-2022	27-Nov-2023	vPvB
53	2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol	UV-350	253-037-1	36437-37-3	27-May-2022	27-Nov-2023	vPvB
54	2-benzotriazol-2-yl-4,6-di-tert-butylphenol	UV-320	223-346-6	3846-71-7	27-May-2022	27-Nov-2023	PBT vPvB

Source: https://echa.europa.eu/authorisation-list

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1. Conclusions

Following an assessment of the available evidence, ECHA considers that uses of UV-328 in articles (domestic or imported) which may pose a risk to the environment that is not adequately controlled will be addressed by other regulatory actions, namely the POP Regulation (EU) 2019/1021.

UV-328 is a PBT and vPvB substance for which no threshold can be determined below which exposure would be safe. There is information that indicates that the use or presence of the substance in articles would lead to releases to the environment. However, the resulting risk is expected to be addressed by the EU POP Regulation.

This will happen when the EU implements the control measures resulting from the listing of UV-328 in Annex A[1] of the Stockholm Convention by including it in Annex I[2] to the EU POP Regulation. This is expected to happen in the first half of 2024.

Therefore, under REACH Article 69(2), ECHA's view is that at present there is no need to prepare an Annex XV dossier for restriction.

AND

Following an assessment of the available evidence, ECHA considers that the use (or presence) of UV-320, UV-327 and UV-350 in articles poses a risk to the environment that is not adequately controlled. (See section 2 for more details).

The presence of these substances in articles has the potential to lead to releases to the environment.

Furthermore, UV-320, UV-327 and UV-350 are vPvB, or vPvB and PBT substances for which no threshold can be determined below which exposure would be safe.

Unlike UV-328 these three phenolic benzotriazoles have not been proposed to be reviewed under the Stockholm Convention. Therefore the EU POP Regulation is not a potential route for their risk management.

Hence, ECHA's view is that the requirements to prepare an Annex XV dossier for restriction (on all or selected) uses of these substances in articles are met. The timing of the restriction dossier development will be identified in the Restriction Roadmap, considering other priorities.

The above conclusions as well as the assumptions and findings in this draft report were subject to a Call for Evidence that took place from 31 May to 18 August 2023. Twelve organisations including national authorities, industry associations and companies provided information that has been incorporated into the report. The additional information received during the Call for Evidence did not impact the conclusions of this report. Majority of the

[1] Chemicals listed in Annex A

[2] Annex I lists the prohibited substances. Article 3 of the POP Regulation prohibits the production, placing on the market and use of substances listed in Annex I.

comments were about UV-328 and related to its upcoming inclusion in the Annex I to the POP Regulation. Product registry information about the four benzotriazoles, their specific uses and concentrations in certain materials were also submitted.

2. Summary of findings

2.1. Identified uses

The four phenolic benzotriazoles are used as UV-absorbers for a wide variety of plastics, rubber, resins and other organic materials[3]. UV-absorbers enhance the durability of a wide variety of polymer materials in various consumer and industrial goods They are also used in paints, coatings and printing inks. Their concentration in polymeric materials is typically 0.1 – 0.5% w/w but in coatings and rubber it can be higher (1 – 3% w/w). UV-328 and UV-327 are commonly used in automotive sector. UV-327 is authorised as additive for food contact plastics in accordance with Regulation (EU) No 10/2011 (with a group migration limit (SMLT) set to 30 mg per kg food for UV-327 and two other benzotriazoles not listed in this report) and as additive for printing inks according to the 21st amendment of the German ordinance for consumer goods.

All four substances are used in plastics[4], electrical and electronic equipment, optical and measuring devices as well as in medical devices including e.g. blood collection tubes, invasive devices and various polymeric materials, but UV-328 is the substance notified in largest numbers to the SCIP database[5] by companies in various industry sectors. The specific articles in which they have been notified to ECHA's SCIP database include, but are not limited to: interior and exterior parts of vehicles, aircraft parts, liquid crystal display (LCD) panels, various rubber items, electrical cables, switches, plugs and sockets, IT and communication equipment, cameras and lenses, plastic film, sheets and labels as well as high-performance polymers and additives for interior and exterior building materials.

According to the Swedish Product Registry, the use of UV-328 and UV-327 has been going down during the past ten years and for UV-320 and UV-350 no tonnages have been registered into the database[6].

Only UV-328 is registered under REACH. In December 2023, there were eleven active REACH registrations with a total tonnage band up to 1 000 tpa[7]. This substance is not manufactured in the EU therefore all registrations are linked to imports, mainly from Asia[8]. Substances in articles notifications under Article 7(2)[9] of REACH have been received for UV-328 and UV-327. Based on ECHA's SCIP data, many notified articles containing these four substances are also imported. ECHA has not received applications for authorisation

[3] UV-328 Risk Management Evaluation Additives for Polymers - The Universal Selection Source – SpecialChem
[4] UV-327 is authorised as additive for food contact plastics
[5] SCIP is the database for information on **S**ubstances of **C**oncern **I**n articles as such or in complex objects (**P**roducts) established under the Waste Framework Directive (WFD).
[6] Swedish authorities data submission during the Call for Evidence
[7] https://echa.europa.eu/registration-dossier/-/registered-dossier/5280/1/2
[8] Estimating the number and types of applications for 11 substances added to the Authorisation List, February 2020
[9] Notification of substances in articles

for any of these phenolic benzotriazoles. Therefore their use in the European Economic Area (EEA[10]) should have stopped by the sunset date of 27 November 2023.

The listing of UV-328 in Annex A[11] of the Stockholm Convention is currently ongoing[12] and it will lead to the discontinuation of its use globally, except in exempted uses such as spare or replacement parts.

The manufacturing and use of the three other benzotriazoles is likely to continue outside the EEA, Switzerland, and UK, where no regulatory limitations are currently foreseen for them.

Therefore, despite their discontinued use in the EEA, as UV-327, UV-350 and UV-320 may potentially substitute UV-328 in some applications and their use may increase in the coming years, UV-320, UV-327 and UV-350 are likely to be present in imported articles.

2.2. Hazards, emissions/releases/exposure and risk

Information on hazards

UV-327 (entry 52) and UV-350 (entry 53) have been included in Annex XIV due to their vPvB properties and UV-328 (entry 51) and UV-320 (entry 54) due to their vPvB and PBT properties.

Other hazard endpoints are not relevant for the Article 69(2) assessments of these substances.

Information on emissions/release/exposure

These four benzotriazoles do not bind into the polymer matrix when they are used as UV-absorbers. Their poor water solubility and non-volatility[13] - that are favourable characteristics in the applications for which they are used - also limit their emissions and releases from articles into the environment.

Only limited information is available on the releases of these benzotriazoles from articles. Environmental exposure during the foreseeable use of an article containing any of them identified during this screening is expected to be limited. Therefore, treatment and disposal of articles at their end-of-life stage are the main life cycle steps that may lead to environmental exposure. Via the call for evidence, Industry representatives noted that releases during end-of-life treatment of some medical devices (e.g. invasive ones) are not expected given that this medical waste is considered, and treated as biohazard.

[10] EEA includes three non-EU countries: Iceland, Liechtenstein and Norway.

[11] Parties must take measures to eliminate the production and use of the chemicals listed under Annex A. Specific exemptions for use or production are listed in the Annex and apply only to Parties that register for them.

[12] Recommendation by the Persistent Organic Pollutants Review Committee to list UV-328 in Annex A to the Convention and draft text of the proposed amendment. In May, the COP agreed to the listing, which should enter into force before the end of 2024.

[13] https://echa.europa.eu/documents/10162/78b46a52-7b7c-c7ae-d5d7-2df3d2ef3a21

The EU waste and sector specific legislations do not address these substances. However, the requirements to separate hazardous components from waste streams will indirectly impact articles containing them in the future when the CLP Regulation[14] revision introduces PBT and vPvB as new environmental hazard classes[15] and Annex III to the Waste Framework Directive[16] has been updated to reflect that. As the identification of e.g. plastics containing these substances for appropriate incineration may not be practically feasible, the risk of such articles being landfilled exists. Therefore a potential for environmental exposure cannot be excluded.

Article 7 of the EU POP Regulation contains provisions related to waste management and Annex IV[17] contains the list of substances subject to those waste management provisions. Once UV-328 is listed in Annex IV to the EU POP Regulation, waste consisting of, containing or contaminated by UV-328 shall be disposed of or recovered for energy, without undue delay and in accordance with Part 1 of Annex V[18] to the EU POP Regulation, in such a way as to ensure that the UV-328 content is destroyed or irreversibly transformed so that the remaining waste and releases do not exhibit the characteristics of a POP substance. Waste containing or contaminated by UV-328 may be otherwise disposed of or recovered in accordance with the relevant Union legislation, provided that the content of the listed substances in the waste is below the concentration limits to be specified in Annex IV[19].

Characterisation of risk

Phenolic benzotriazoles are not readily or inherently biodegradable and they are therefore considered persistent. Such substances remain in the environment for long periods and have a high potential to accumulate in biota. They are of a specific concern because their long-term effects are rarely predictable. Once these substances have entered the environment, exposure to them is very difficult to reverse, even if their releases/emissions are stopped.

Due to the low water solubility (< 1 mg/l) and high adsorption coefficient (> 5 for UV-328), these benzotriazoles are most likely to be found in the soil and sediment compartments if they are released into the environment. The Stockholm Convention Risk Profile[20] on UV-328 indicates that the substance is likely to be transported long distances that may lead to significant adverse environmental effects. Several studies included in the Risk Profile report the presence of UV-328 in various remote areas. Due to chemical similarities of the three other phenolic benzotriazoles they can be expected to behave the same way as UV-328 in the environment.

[14] Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP Regulation)

[15] Commission sets up rules to identify endocrine disruptors and long-lasting chemicals and to improve labelling

[16] Directive 2008/98/EC

[17] ANNEX IV List of substances subject to waste management provisions set out in Article 7

[18] Waste Management Part 1 Disposal and recovery under Article 7(2)

[19] List of substances subject to waste management provisions set out in Article 7

[20] UV-328 Risk profile adopted by the Persistent Organic Pollutants Review Committee

2.3. Justification that action is required on an EU-wide basis

The evidence collected from various sources[21] used for this screening report clearly demonstrates that the four phenolic benzotriazoles are currently present in a wide variety of articles used across all EU Member States.

2.4. Justification that the proposed restriction is the most appropriate EU-wide measure

The use of UV-328 is foreseen to be discontinued globally under the Stockholm Convention Annex A listing in the coming years.

The COP[22] decided on the listing of UV-328 in Annex A to the Stockholm Convention, including any specific exemptions[23], during the 11th COP meeting in May 2023, with the entry into force expected to take place in November-December 2024[24]. In order for the EU to implement its obligations under the Convention, the European Commission will amend Part A of Annex I to EU POP Regulation, with an expected adoption and publication in the first half of 2024.

Following the listing of UV-328 in Annex A of the Stockholm Convention, Parties to the Convention are required to take measures to eliminate the production and use of UV-328. Parties, including the EU, may register for specific exemptions included in Annex A to allow for the manufacturing and use of UV-328 for certain applications. If the EU would like to implement specific exemptions[25] to allow the import and placing on the market of articles containing UV-328 it needs to register for them under the Convention and include them in the entry for UV-328 in Annex I to the EU POP Regulation.

With regard to UV-320, UV-327 and UV-350, the use of these three substances is not foreseen to have any regulatory limitations outside the EEA, Switzerland and the UK. Therefore, the primary reason to act on a Union-wide basis is to effectively reduce the import of these substances in articles and thus their emissions into the environment across all EU Member States. The emissions are most likely during the end-of-life of articles and the current waste legislation is not considered to be sufficient to prevent the related risk from the articles containing these substances.

[21] Annex XI Reports: UV-328, UV-327, UV-350 & UV-320, UV-328 Risk Profile & Risk Management Evaluation, SCIP database, SPIN database, SciFinder[n]

[22] The Conference of the Parties (COP) is the governing and decision-making body of the Convention.

[23] POPRC.18/11/Add.2

[24] A formal notice that the Depositary of the Convention sends to all Member States, non-member States, the specialized agencies of the United Nations, and the relevant secretariats, organizations and UN offices. The notification provides information on the Convention, including actions undertaken.

[25] Further details on the relationships between the Stockholm Convention, the POP Regulation and REACH in the areas of restrictions and authorisations are available in the common understanding paper

2.5. Other information

Available information on alternatives

ECHA's 2020 study[26] on substances on the authorisation list indicates that there are several suitable alternatives to UV-328 that are already commercially available, some of which are supplied by the registrants of UV-328. The Call for Evidence feedback also confirmed that alternatives are available for these benzotriazoles. The suppliers are confident that downstream users will switch to materials containing alternatives but this will happen after the sunset date. There are some concerns that UV-328 might be substituted by other phenolic benzotriazoles – not limited to the ones covered by this report[27] – that may have a similar hazard profile. Due to the fact that regulatory limitations for the use of UV-320, UV-327 and UV-350 are foreseen only in the EU/EEA, Switzerland and the UK, this could lead to regrettable substitution in other regions.

The Stockholm Convention Risk Management Evaluation[28] discusses in detail some available alternatives to substitute UV-328 as a UV-absorber in plastics, paints and coatings as well as other applications such as adhesives and sealants. It also notes that the selection of alternatives can be time-consuming due to product qualification testing and technical issues (e.g. optical or processing performance).

Socio-economic Assessment of Proposed Restriction

The fact that no application for authorisation has been submitted for any of these substances indicates that EU companies currently using them in articles will continue their production with available alternatives. Therefore, a potential restriction on articles would have impact only on imported articles. Some of them may potentially become unavailable if their producers are not able or willing to update their products to be EU compliant if a restriction in articles is introduced. This will concern UV-320, UV-327 and UV-350 that will have regulatory limitations for their use only in the EEA. The discontinuation of the imports of complex objects or components containing these three substances may negatively affect some sectors that rely on imports for their production or sales.

A specific issue raised during the Stockholm Convention stakeholder consultations[29], is the impact of the UV-328 substitution to automotive sector. Due to safety testing of parts for automobiles, motorcycles, agricultural vehicles, construction machinery and industrial vehicles, a continued use of the substance is needed to ensure availability of replacement parts. The same may apply also to some medical equipment, electric and electronic instruments and housing equipment. Further information about the exemptions under the Annex A listing is available on the Stockholm Convention website[30]. The Stockholm Convention Risk Management Evaluation of UV-328 notes that no specific information is available on substitution costs.

[26] Estimating the number and types of applications for 11 substances added to the Authorisation List, February 2020

[27] SUMMARY REPORT OF THE 33rd PBT EXPERT GROUP MEETING

[28] Risk management evaluation for UV-328, UNEP/POPS/POPRC.18/11/Add.2 adopted in November 2022

[29] Annex F information provided by Parties and observers to the Stockholm Convention, February 2022

[30] Eighteenth meeting of the Persistent Organic Pollutants Review Committee, POPRC.18

Background and scope of Article 69(2) screening

This screening report is prepared according to Article 69(2) of REACH Regulation (EC) No. 1907/2006. The article requires that ECHA, after the sunset date has passed for a substance included on the Authorisation List (Annex XIV), considers if risks from the use of the substance in articles are adequately controlled and, if this is not the case, prepares an Annex XV restriction dossier.

Thus, this screening report is targeted at the potential release or exposure to the Annex XIV substance(s) from an article throughout its lifecycle (including the waste stage) and whether such use(s) should be restricted. The report is focused on the human health and/or environmental hazards due to which the substance is placed on the Annex XIV. Other hazards are not required to be taken into account for the purpose of the screening. Similarly, in the event ECHA proposes that an Annex XV dossier for restrictions is prepared, the scope of the work will be restricted to the risks arising from the Annex XIV intrinsic properties only unless the scope is expanded on request by the European Commission to include other endpoints. It is to be noted that REACH restrictions do not apply in certain cases. These include manufacture and placing on the market or use of a substance in scientific research and development, risks to human health of the use of the substance in cosmetic products, and when a substance is used as an on-site isolated intermediate.

In most cases, risks stemming from the incorporation of the substance into an article are not in the scope of this screening report. Incorporation of a substance in articles has to be authorised, unless this use is exempted in accordance with Article 56(1) of REACH[31]. The incorporation process carried out in third countries is outside the scope of EU legislation (and REACH Authorisation). However, it should be noted that articles, if imported to the EU, are within the scope of this investigation. The incorporation is regarded to cover two type of uses[32]:

a) The substance is incorporated into an article during its production, or

b) The substance, alone or in a mixture, is incorporated into/onto an existing article (isolated or incorporated in a complex object) at a later stage (e.g., coatings, primers, adhesives, sealants) and become an integral part of the article (or of the complex object).

[31] Q&A ID: 0564: https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/ids/0564 Note that ECHA will investigate for this report whether applications for authorisation/authorisation decisions cover the incorporation of the substance into an article and possible cumulative effects of the substance due to authorisations.

[32] https://echa.europa.eu/documents/10162/23036412/articles_en.pdf/cc2e3f93-8391-4944-88e4-efed5fb5112c